

REMARKS

In the Office Action dated December 9, 2008, claims 28-37 are pending. Claims 28-35 are under consideration in conjunction with elected SEQ ID NOS: 11-12. Claims 36-37 have been withdrawn from consideration as drawn to non-elected subject matter. Claims 28 and 31-34 are objected to for certain alleged informalities. Claims 28-35 are rejected under 35 U.S.C. §112, second paragraph, as allegedly indefinite. Claim 28-35 are rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the enabling requirement. Claims 28-35 are also rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. Claims 28-35 are further rejected under 35 U.S.C. §102(b) as allegedly anticipated by WO 94/28140.

This Response addresses each of the Examiner's rejections and objections. Applicants therefore respectfully submit that the present application is in condition for allowance. Favorable consideration of all pending claims is therefore respectfully requested.

Claim Amendments:

Independent claim 28 has been amended to delete references to non-elected SEQ ID NOS: 9 and 10, and to recite specific stringency conditions described on pages 54-55 of the specification. Further, claim 28 has been amended to add the term "at least" in front of the percentage of sequence identity or similarity, which is supported by the specification, e.g., page 30, lines 12-19. Additionally, claim 28 has been amended to add the term "after optimal alignment" in part (iv), consistent with part (ii) and supported by the disclosure on page 32, lines 23-29 of the specification, for example.

Other claim amendments are discussed in the following remarks.

No new matter is introduced.

Claim Objections

Claims 28 and 31-34 are objected to for certain alleged informalities.

Specifically, claim 28 is objected to for reciting non-elected SEQ ID NOS: 9 and 10.

Applicants have amended claim 28 to delete SEQ ID NOS: 9 and 10. Applicants reserve the rights to pursue subject matter relating to SEQ ID NOS: 9 and 10 in a divisional application.

Claims 28 and 31-34 are also objected to for some other alleged informalities.

Applicants believe that the amendments presented herein have addressed these informalities.

Claim 33 is objected to under 37 C.F.R. §1.75(c) as an improper dependent claim for allegedly failing to further limit the subject matter of a previous claim. Claim 33 has been canceled, and dependent claims 34 and 35 have been amended accordingly in their dependencies.

In view of the foregoing, the Examiner's objections to the claims are obviated.

Withdrawal of the objections is respectfully requested.

35 U.S.C. § 112, Second Paragraph

Claim 28 is rejected under 35 U.S.C. § 112, second paragraph. The Examiner alleges that the recitation of "high stringency conditions" in part (iv) of claim 28 is indefinite, because the temperature and washing conditions are not defined.

Applicants have amended claim 28 to recite the specific conditions described on pages 54-55 of the specification. No new matter is introduced.

Claim 35 is rejected as indefinite for reciting "a progeny thereof".

Applicants have amended claim 35 to recite "wherein said rose progeny comprises said nucleic acid molecule" at the end of claim 35, as suggested by the Examiner.

In view of the foregoing, the rejections under 35 U.S.C. § 112, second paragraph, are obviated. Withdrawal of the rejections is respectfully requested.

35 U.S.C. § 112, First Paragraph (Enablement)

Claims 28-35 are rejected under 35 U.S.C. § 112, first paragraph, for failing to comply with the enablement requirement.

Specifically, respecting claim 28, the Examiner contends that the specification does not reasonably provide enablement for part (ii), (iv) or (v) of the claim.

With regard to the rejection relating to parts (ii) and (v) of claim 28, the Examiner alleges that the present specification fails to provide guidance on how to make nucleic acids having 80% sequence identity with SEQ ID NO: 11, or encoding amino acid sequences having 90% similarity to SEQ ID NO: 12, which encode an F3'5'H protein. The Examiner contends that it would require undue experimentation for those skilled in the art to practice the claimed invention.

Applicants respectfully disagree and submit the following.

In the first instance, the specification provides ample guidance and a number of exemplification for how to isolate a nucleic acid encoding F3'5'H from plant species. For example, in the experiments described in the present application, nucleotide sequences encoding F3'5'H from kennedia (Clone Kenn#31), gentian (Clone Gen#48), salvia (Clones Sal#2 and Sal#47), sollya (Clone Soll#5), butterfly pea (Clone BpeaHF2), pansy (Clones BP#18 and BP#40), petunia (Clone petHf1 and petHf2) and lavender (Clone LBG) have also been cloned, and have been further expressed in petunia, carnations or roses (see Table 14, page 119 of the specification). Notably, clone BP#18 from pansy has 82% nucleotide sequence identity with

SEQ ID NO: 11 (see Table 16, page 123) and 94% amino acid similarity to SEQ ID NO: 12 (see Table 17, page 124), and therefore serves as an additional example (besides SEQ ID NOS: 11/12) of a nucleic acid molecule that supports the scope of the claims.

Moreover, the present specification discloses that detection of the enzymatic activity of F3'5'H can be based on detecting levels of delphinidin or delphinidin-based molecules by conventional chromatographic methods including TLC and HPLC (for example, page 7, line 13-16; page 51, line 11-14). Therefore, the skilled artisan would be able to also readily evaluate and determine whether an isolated nucleic acid molecule encodes a protein that has F3'5'H activity, without undue experimentation.

With regard to part (iv) of claim 28, the Examiner contends that because the term "high stringency conditions" is not defined, any nucleotide sequence (including sequences unrelated to F3'5'H) would hybridize to a nucleotide sequence encoding the polypeptide of SEQ ID NO: 12.

Applicants direct the Examiner's attention to the amendments to claim 28, now reciting specific high stringency conditions. Applicants further note that the specification provides a number of examples demonstrating isolation of F3'5'H-encoding clones based on hybridization techniques.

Accordingly, it is respectfully submitted that it would not require undue experimentation for those skilled in the art to obtain the nucleic acid molecule of claim 28, as presently recited.

Claim 32 is rejected allegedly because the specification fails to teach making a genetically modified plant in any manner other than transforming a plant with a nucleic acid encoding the F3'5'H protein of SEQ ID NO: 12. It appears that the Examiner has interpreted the

claim as encompassing a plant having an endogenous F3'5'H molecule which is somehow induced to overexpress thereby altering the color of the plant.

Applicants have amended claim 32 to delineate that the nucleic acid molecule is "heterologous to said plant and said progeny thereof" (i.e., exogenously introduced). It is respectfully submitted that this amendment has obviated the rejection of claim 32.

Claims 32-35 are rejected as not enabled, apparently because of the recitation of a "complementary" form in base claim 28.

Applicants have amended claim 28 to delete the term "complementary" in the preamble, and to reword part (iv) of claim 28, which fully addresses the rejection.

In view of the foregoing, the enablement rejection of claims 28-35 under 35 U.S.C. § 112, first paragraph, is obviated. Withdrawal of the rejection is respectfully requested.

35 U.S.C. § 112, First Paragraph (Written Description)

Claims 28-35 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. Essentially, the Examiner contends that the genus of nucleic acid molecules as claimed in claim 28, are not sufficiently supported by a disclosure of only one species, i.e., SEQ ID NOS: 11/12.

Applicants first note that F3'5'H is an enzyme which has been characterized in the art prior to the filing of the present application, at least for several plant species. For example, two nucleotide sequences from petunia (referred to in the present application as SEQ ID NO: 1 and NO: 2) were cloned and expressed in petunia (see International Patent Application No. PCT/AU92/00334, and Holton *et al.*, Nature, 366: 276-279, 1993a), tobacco (see International Patent Application No. PCT/AU92/00334), and carnations (see International Patent Application

No. PCT/AU96/00296), and were shown to exhibit F3'5'H activity.

Further, Applicants respectfully submit that part (iv) of claim 28 has been amended to recite high stringency conditions, further defining the claimed genus.

Moreover, as submitted above, the specification describes a number of nucleic acids encoding F3'5'H from various plant species. At least one of these species clearly supports the claimed genus of claim 28 – i.e., clone BP#18 (SEQ ID NOS: 9 and 10) from pansy has 82% nucleotide sequence identity with SEQ ID NO: 11 (see Table 16, page 123) and 94% amino acid similarity to SEQ ID NO: 12 (see Table 17, page 124). This clone is also believed to hybridize to SEQ ID NO: 11 under the presently defined hybridization conditions. Other exemplified clones also share significant homologies with SEQ ID NO: 11 (and the encoded SEQ ID NO: 12), and are believed to also hybridize to SEQ ID NO: 11 under certain stringency conditions.

In view of the prior characterization of petunia enzymes in the art, the multiple F3'5'H-encoding clones disclosed in the specification, and at least two species (SEQ ID NOS: 9/10 and 11/12) that support the claimed genus, Applicants respectfully submit that the genus of nucleic acids of claim 28 have been adequately described by the instant disclosure in a manner that fully satisfies the written description requirement. As such, the written description rejection of claims 28-35 under 35 U.S.C. § 112, first paragraph, is obviated. Withdrawal of the rejection is respectfully requested.

Rejections under 35 U.S.C. § 102(b)

Claims 28-35 are rejected under 35 U.S.C. §102(b) as allegedly anticipated by WO 94/28140. The Examiner contends that because the hybridization conditions are not defined in claim 28, the claim would encompass unrelated nucleic acids, including the sequence disclosed

in WO 94/28140.

Applicants respectfully submit that claim 28, as amended, recites specific high stringency conditions. There is no indication or evidence that would suggest that the sequence disclosed in WO 94/28140 would hybridize to SEQ ID NO: 11 under the recited conditions. Accordingly, the §102(b) rejection based on WO 94/28140 is overcome, and withdrawal thereof is respectfully requested.

Conclusion

In view of the foregoing amendments and remarks, it is firmly believed that the subject application is in condition for allowance, which action is earnestly solicited.

Respectfully submitted,



Xiaochun Zhu
Registration No. 56,311

SCULLY, SCOTT, MURPHY & PRESSER, P. C.
400 Garden City Plaza-STE 300
Garden City, New York 11530
(516) 742-4343
XZ:ab